FREEDOM OF INFORMATION (FOI) SUMMARY FOR ORIGINAL AND SUPPLEMENTAL NEW ANIMAL DRUG APPLICATIONS (NADA)

I. PURPOSE

This document provides instructions on how to use the office template to prepare a Freedom of Information (FOI) Summary for an original or supplemental New Animal Drug Application (NADA). This document also describes the information we include in the FOI Summary for original and supplemental NADAs other than labeling and regulatory supplements.[1]

[1] Regulatory supplements are supplements for labeling changes initiated by the Office of Surveillance and Compliance but submitted to ONADE. Labeling and regulatory supplements, as defined in draft regulation 21 CFR 514.8(c)(3), are covered elsewhere and are not covered in detail in this document. Consult your team leader or division director and the P&P Manual for P&Ps on labeling and regulatory supplements.

II. SUMMARY OF PROCEDURE

A. An FOI Summary provides the public a summary of the safety and effectiveness data on which we based our decision to approve the new animal drug.

B. We prepare an FOI Summary for each approved original NADA and each supplemental NADA that involves a change to the Code of Federal Regulations (CFR), does not change the CFR but involves significant review of data, or has a significant impact on how the drug is used.[2]

C. Include the relevant FOI Summary language from the technical section complete letters found in the Investigational New Animal Drug (INAD) file.

D. For applications that sponsors plan to submit as Administrative NADAs, the division responsible for review of the Target Animal Safety and Effectiveness technical sections will: 1) create a "Q" submission under the INAD when the sponsor submits the last technical section (usually an "M" submission), 2) assemble the FOI Summary, and 3) issue an acknowledgement letter to the sponsor enclosing a copy of the FOI Summary. A copy of the FOI will be included in Folder A of the approval package when it is prepared.

E. For non-Administrative NADAs, the division responsible for review of the Target Animal Safety and Effectiveness sections of the application will: 1) begin to prepare the FOI Summary when they receive the application and update the FOI language as reviews are completed for each section, and 2) include the complete FOI Summary in Folder A of the approval package.

III. WHY DO WE NEED AN FOI SUMMARY?

After we publish an approval of an original or supplemental NADA in the Federal Register, we are required to make "immediately available for public disclosure", among other things, a summary of "the safety and effectiveness data and information submitted with or incorporated by reference in the NADA file". We must make this disclosure "unless extraordinary circumstances are shown".[3]

[2] Some labeling or regulatory supplements may involve a change to the CFR but may have no significant impact on the use of the drug. Therefore, they do not require an FOI Summary. Consult your team leader or division director and the P&P Manual for P&Ps on labeling and regulatory supplements.

[3] Although the regulations do not use the specific term "FOI Summary," FDA uses this term to describe the summary we prepare pursuant to 21 CFR 514.11(e). We refer to this document as an FOI Summary because

IV. WHAT NADA APPLICATIONS NEED AN FOI SUMMARY?

ONADE prepares an FOI Summary for each approved original application.[4] In addition, it is our current practice to prepare an FOI Summary for a supplemental NADA that:

- changes the existing CFR,[5]
- does not change the CFR but involves significant review of data, or
- does not change the CFR but has a significant impact on how the drug is used.

If you have questions, about which applications need FOI Summaries, consult your team leader.

V. WHO PREPARES AN FOI SUMMARY?

We will prepare the final version of the FOI Summary.[6] Generally, a reviewer in the Target Animal Safety Division will be responsible for preparing the FOI Summary, but the preparer may be any other individual designated by office, division, or team procedures. If the reviewer has questions about who prepares the FOI Summary, they should consult with their team leader or division director.

VI. GENERAL PRINCIPLES FOR FOI SUMMARIES

A. The FOI Summary should:

1. Be detailed

it contains the information that we would disclose in response to an information request under the Freedom of Information Act.

[4] See 21 CFR 514.11(e).

[5] Some labeling or regulatory supplements may involve a change to the CFR but may have no significant impact on the use of the drug. Therefore, they do not require an FOI Summary. Consult your team leader or division director and the P&P Manual for P&Ps on labeling and regulatory supplements.

[6] FDA regulations allow either CVM or the sponsor (with CVM review and revision) to prepare the FOI Summary (21 CFR 514.11(e)(2)(ii)). Sponsors often submit a draft FOI Summary with each applicable technical section (under the INAD) or with a non-administrative original or supplemental NADA. It is ONADE policy that we prepare the FOI Summary.

The FOI Summary should summarize effectiveness and safety data and other information in sufficient detail to show the basis on which the agency approved the NADA. Be clear and accurate.

For supplemental NADAs, you (the preparer) should only include data relevant to the approval of the current supplemental NADA in the FOI Summary. The FOI Summary may include references to data reviewed and summarized in previous FOI Summaries.

2. Be consistent with all reviews conducted for the approval

   If there are differences between the FOI Summary and the related reviews of the data, explain these differences in the "Q" submission. In the rare instance that they are discovered during the preparation of the approval package, document them in the Memorandum Recommending Approval (MRA).

3. Be internally consistent

   For example, always reference the new animal drug in the same manner, and make sure that information you include in the text matches that in the tables and the tabular values are arithmetically valid.

4. Define acronyms the first time they appear in the document

5. Reference previous approvals when needed

   If the FOI Summary includes references to previous approvals, each reference should include the NADA number and the date of the FOI Summary that contains the information you reference (i.e., refer to the FOI Summary for NADA XXX-XXX dated DATE).[7] If the FOI Summary you are referencing does not have a date, use another reference (i.e., approval letter, or, if you cannot find a dated approval letter, a FEDERAL REGISTER notice). Clearly identify the document to which you refer and its date (i.e., NADA XXX-XXX, approved DATE or approval of NADA XXX-XXX, as published in the FEDERAL REGISTER (volume number FR page number) on DATE).

[7] ONADE uses the date of the FOI Summary because it is most closely associated with the information being referenced. Some older FOI Summaries contain approval dates or FR notice dates. In general, the date on the front page of the FOI Summary is the same as the date on the approval letter. In most cases, the FR notice date will not match the approval letter (or FOI Summary) date.

6. Use plain language

   The purpose of the FOI Summary is to explain the basis for the approval to the public. Write it using plain language [www.plainlanguage.gov].

B. Do not include trade secrets or confidential commercial information in the FOI Summary

The Freedom of Information Act exempts trade secrets and confidential commercial information from disclosure.[8] In addition, Federal law prohibits the disclosure of trade secrets submitted to FDA.[9] If you have questions regarding what information to include in the FOI Summary, discuss them with your team leader and the Center's FOI Officer.

VII. PREPARING THE FOI SUMMARY LANGUAGE FOR EACH TECHNICAL SECTION

Each technical section complete (TSC) letter under the INAD should include the relevant FOI Summary language for that section. The division issuing the technical section complete letter will determine who (within their division) will prepare the FOI Summary language. If time permits, the reviewer of the technical section may communicate with the sponsor informally before issuance of a TSC letter to inform the sponsor about the language that they have prepared to incorporate into the FOI Summary for that technical section. If the sponsor disagrees with FOI Summary language that is included in a TSC letter and wants changes (after the letter is issued and any time before approval of the new animal drug), we may have to reopen the relevant technical section. Remember that the FOI Summary is a CVM document because its purpose is to describe our basis for recommending approval of a new animal drug. Thus, the reviewer needs to make the final decision regarding which information to include in the FOI Summary.

The Division of Human Food Safety should provide the Target Animal Safety division with an electronic copy of the FOI Summary language when they issue their TSC letter. The primary reviewer should be aware that if the Human Food Safety technical section complete (including the Human Food Safety section of the FOI Summary) is the last

[8] 5 USC §552(b)(4). 21 CFR 20.61.
[9] See Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 USC §331(j)), 18 USC §1905, and 21 CFR §20.61.

"P" submission, it may delay the completion of the All Other Information and Labeling ("M") submissions, as well as the FOI Summary ("Q") submission.

VIII. PREPARING THE FOI SUMMARY DOCUMENT

A. Administrative NADAs

1. Create a "Q" submission

   You, the division responsible for review of the Target Animal Safety and Effectiveness technical sections, should create a "Q" submission under the INAD when the sponsor submits the last technical section (usually an "M" submission).[10] You should request that the DCU assign the "Q" submission the same due date as the last "M" submission.

2. Assemble the FOI Summary document

   When you create the "Q" submission, you should assemble the FOI Summary from the FOI Summary language contained in each technical section complete letter and prepared for any pending submissions. Issues related to factual errors and editorial changes should have been resolved with each technical section. Focus on consistency and completeness at the "Q" stage. You should discuss any changes you make to the FOI Summary language provided by a consulting reviewer with that reviewer and document the discussion and any changes in the administrative file. You should then review the FOI Summary for consistency, accuracy, and readability. If time permits, you may communicate with the sponsor informally before issuance of a "Q" letter to allow them to review the FOI Summary document.

3. Preparing the "Q" submission final action package

   Final out the "Q" submission following current procedures.[11] If we issue a TSC letter for the last technical section (i.e., the last "M" submission), the appropriate final action for the "Q" submission is to issue an acknowledgement letter to the sponsor enclosing a copy of the FOI Summary document. The letter should inform the sponsor that they may request changes to correct typographical errors. If we cannot issue a TSC letter for the last technical section, your review

[10] See the STARS Forms page for the Agency Initiated Submission Request Form.
[11] See P&P 1243.3030.

should state that we could not complete the "Q" submission because we could not issue a TSC letter for the last technical section. In this case, the appropriate final action is FNR/memo. The "Q" submission final action package should include a copy of the draft FOI Summary document and your review. Your review should summarize the extent and substance of the preparation of the FOI Summary document up to the point that you stopped review of the last technical section. Type "Draft Incomplete – See Review" and the date in the date field of the FOI Summary title page.

4. Requests for changes[12]

   If the sponsor contacts us to let us know there are errors, you will review the request and may reopen the relevant technical section(s). There is no guarantee the proposed changes will be incorporated into the FOI Summary.

   If the sponsor proposes minor editorial changes that you determine will make the FOI Summary more accurate or identifies factual errors, then we will not reopen relevant technical sections. Incorporate those minor changes into the FOI Summary that you include in the approval package.

B. Non-Administrative NADAs

For non-administrative NADAs, you should begin to prepare the FOI Summary document when you receive an application, and continue building the FOI Summary document as you and the consulting reviewers complete your reviews of each technical section. If applicable, incorporate any FOI Summary language that was previously agreed upon in technical sections completed under the INAD. Time permitting, you may share a copy of your FOI Summary document with the sponsor and tell the sponsor that they may request changes to correct typographical errors.

You should include the complete FOI Summary in Folder A of the approval package.

[12] We will close out the "Q" submission if the sponsor requests changes that result in reopening a technical section while the "Q" submission is still open. The appropriate final action for the "Q" submission is FNR/memo.

IX. CONTENTS OF THE FOI SUMMARY

Use the office template for the NADA FOI Summary. Instructions for finding and using templates are located on the ONADE Reviewer's Reference Page under Review Aids/Approved Products on the ONADE Templates page.

This section describes the contents of each section of the FOI Summary in more detail than the template. Refer to this section as you use the FOI Summary template.

A. General instructions for using the FOI template

1. Words not in italics or brackets, (i.e., < >), in the FOI are boilerplate and should be included in your FOI verbatim.

2. Words in bracketed italics may provide instruction, describe the information you should provide, or may give examples of the type of information that you should include in a particular portion of the FOI.

3. Where you see brackets or shaded areas, you will provide information relating to your specific application.

B. Title Page

1. Date of Approval

   Leave this blank in the final version. The Document Control Unit (DCU) will date stamp the FOI Summary with the same date as the approval letter.

2. Proprietary Name

   The proprietary name is the exclusive name the sponsor or distributor assigns to a drug substance or the drug product. It is more commonly known as the trade name and is often trademarked. For example, different sponsors market amoxicillin as, "AMOXI-SOL", "AMOXI-BOL", and "ROBAMOX-V." The proprietary name should be identical to the product label. Use it consistently throughout the FOI Summary.

   The trademarked portion of the proprietary name(s) (i.e., the part preceding the trademark symbols ® or ™) should appear in all capital letters without the trademark symbols. You should write the remaining part of the name in lower case letters with the first letter of each word capitalized. If there is no trademark

symbol, then you should write the entire proprietary name in lower case letters with the first letter of each word capitalized. For example:

- Quest® Gel would appear as QUEST Gel
- Component® TE-H with Tylan® would appear as COMPONENT TE-H with TYLAN
- Tri-Heart® Plus Chewable Tablets would appear as TRI-HEART Plus Chewable Tablets
- Sentinel® Flavor Tabs® would appear as SENTINEL FLAVOR TABS
- Penicillin G Potassium, USP, which is not trademarked, would appear as Penicillin G Potassium, USP.

3. Established Name

   The United States Adopted Names (USAN) Council usually assigns the established name.[13] Amoxicillin, florfenicol, and roxarsone are some examples of established names. The established name should be identical to the product label. Use it consistently throughout the FOI Summary.

4. Dosage Form

   The dosage form refers to the physical description of the approved manufactured product. For example, aerosol, enteric-coated capsule, cream, emulsion, granule, implant (pellets), infusion, inhalant, paste, soluble powder, solution for injection, suspension, chewable tablet, or Type A medicated article.

5. Indication(s) or Effect(s) of Supplement

   The indication(s) or effect(s) of supplement in the FOI Summary refers to the indications (for an original application) or changes (for a supplemental application) being approved in this application. For an original application, the indication(s) you include in the FOI Summary should be identical to those on the label. For supplemental applications, list the change(s) being approved (i.e., describe the new indication, new species, new route(s) of administration, new

[13] See 21 CFR 299.4.

dosage(s), or label changes). The effect(s) of supplement should be descriptive enough to identify which indication(s) and/or species are affected by the supplemental approval. For example, a supplemental NADA to reduce a withdrawal time from 7 to 0 days would read, "To reduce the withdrawal time from 7 to 0 days in turkeys." For the title page, you may paraphrase the indication(s) or effect(s) of supplement if needed, to ensure that the indication(s) or effect(s) of supplement fit(s) on one page.

6. Sponsor's Name

   Copy the sponsor's name exactly as it appears in 21 CFR 510.600(c).

C. Header

The header will appear on all pages (except the cover page) of the FOI Summary. To insert the NADA number in place of <XXX-XXX> in the Header, select View → select Header and Footer. This will open the header so you can insert the NADA number.

D. Table of Contents

The template automatically generates the Table of Contents (TOC). Only the first two heading levels will appear in the TOC.

After you complete the body of the FOI Summary, you need to update the TOC headings and page numbers. To update the TOC, move the mouse cursor over one of the lines in the TOC and click the right mouse button. Select "Update Field" and choose "Update entire table."

E. General Information

1. Sponsor, their address, Drug Labeler Code, and U.S. Agent

   If this is not the first approval for a sponsor, copy the sponsor name, address, and drug labeler code exactly as it appears in 21 CFR 510.600(c). Use the listing in the electronic CFR to obtain the most recent information.[14] If this is a sponsor's first approval, see your team leader for assistance.

[14] The electronic CFR (e-CFR) provides the most up to date information. It is a different site than the online CFR, which is an electronic copy of the most recent printed CFR (issued in April of each year).

If the sponsor does not reside or have a place of business within the U.S., insert the name and address of the authorized U.S. agent.[15] Delete the field if not applicable.

2. Proprietary Name(s) and Established Name(s)

   These sections should be the same as described above for the title page.

3. Pharmacological Category

   This section describes the action of the drug product (e.g., anticoccidial, antimicrobial, or antiparasitic).

4. Dosage Form(s)

   This section should be the same as described above for the title page.

5. Amount of Active Ingredient(s)

   This section desscribes the amount of drug(s) per tablet, mL, percentage, or other measure of concentration.

6. How Supplied

   This section describes the size and description of the containers (e.g., 50 and 100 mL vials).

7. How Dispensed

   This section identifies whether this is a prescription (Rx), over-the-counter (OTC), or veterinary feed directive (VFD).

8. Dosage

   This section describes the approved dose, frequency, and duration of treatment as printed on the approved labeling.

[15] 21 CFR §514.1(a).

9. Route(s) of Administration

   This section describes the way to administer the product. For example, dermal, immersion, implantation, inhalation, intramuscular injection, insertion, instillation, intramammary, intranasal, ocular, oral, otic, or topical.

10. Species/Class(es)

    The information included here should match the description in the product labeling. Some approvals apply to a specific class within a species (e.g., lactating dairy cattle). If there is no class limitation, enter the species in plain language (e.g. dogs rather than canine).

11. Indication(s)

    Copy the information for this section exactly from the approved product labeling. For an original approval, list all indications. For supplemental NADAs, you may abbreviate the list to include only the indications to which the supplement applies. If you include all of the previously approved indications with the new or modified indications, then you should highlight (by bolding) the new or modified indications so that the new or modified indications are readily distinguishable. In the rare instance that the supplement does not apply to a specific approved indication (e.g., a change in Acceptable Daily Intake [ADI]), you should include a statement that reads, "There was no change in the approved indications."

12. Effect(s) of Supplement

    If this is a supplemental approval, this section should briefly describe the changes we are approving. For original approvals, you should delete this row from the General Information table.

F. Effectiveness

1. Introductory paragraph

   You may insert an introductory paragraph before the dosage characterization section if it provides additional relevant information.

2. Dosage Characterization

Sponsors do not have to demonstrate dosage characterization by substantial evidence. This section should provide a narrative summary of the individual studies, literature, or other information that explains how the dosage or dosage range was selected. For new animal drugs intended to affect the structure or function of an animal (i.e., production drugs) this section should also include a summary of the information provided to characterize the critical aspects of the dose relationship relevant to the dose or dose range selected. Examples of production drugs include melatonin use in mink, follicular stimulating hormone for super ovulation, and monensin for feed efficiency. If individual studies are included, the narrative should include, where applicable, the name(s) of clinical investigator(s), location(s) of study (city and state only), a brief description of the protocol or study design, number of animals, and study results. If you include published literature, you should list references at the end of this section.

3. Substantial Evidence

This section describes the adequate and well-controlled effectiveness study or studies that support FDA's decision to approve the new animal drug. You should describe these studies in general terms using an outline format. You may choose to follow the sample outline in Appendix A of this guide. Check with your team leader if you have questions about which studies to include in the FOI Summary.

At a minimum, the study information should include a full identification of the study including name(s) of clinical investigator(s), location(s) of study (city and state only), study type, a brief outline of the protocol, number of animals, and study results. Do not include any information that could lead to identification of the animal owner.

If you include information in the FOI Summary from more than one study, use the same format to summarize each study. You should summarize a multi-location field study for which study results are pooled to assess statistical significance as a single study. The best way to provide study results may be in tables. If you use tables, you may number them consecutively throughout the entire document or consecutively within each section.

The level of detail you provide should allow a general understanding of how each study was performed and the results of each study. For example, if a study uses a 6-point scoring system to evaluate an endpoint, provide enough description so that readers who are not familiar with that scoring system can

interpret numerical summaries in the results section. It is not necessary to describe all aspects of the study.

4. Supplemental approval information

   Some supplemental NADAs may not include dosage characterization information or new studies to demonstrate effectiveness, because they reference information from previous approvals. In these cases, you should use the language in the template, and include the NADA number and date of the FOI Summary that contains the information you reference.

G. Target Animal Safety

The Target Animal Safety section describes the safety studies that support FDA's decision to approve the new animal drug. You should describe these studies in general terms using an outline format. Check with your team leader if you have questions about which studies to include in the FOI Summary.

The basic study information you provide should include a full identification of the study including name(s) of the study director, location(s) of study (city and state only), study type, brief outline of the protocol, number of animals, and study results. Do not include any information that could lead to identification of the animal owner.

The best way to provide study results may be in tables. If there is more than one study, use the same format for each of the studies. If you use tables, you may number them consecutively throughout the entire document or consecutively within each section.

As with the effectiveness data, the level of detail you provide for each study should allow the reader to understand how each study was performed and to understand the results of each study. It is not necessary to describe all aspects of the study.

For supplemental NADAs that do not include new target animal safety studies, you should use the language in the template, and include the NADA number and date of the FOI Summary that contains the information you reference.

H. Human Food Safety

1. Non-food producing animals

If the product is for use in non-food producing animals, then include the standard language in the template explaining that we did not require human food safety data.

2. Food-producing animals

   If the product is for use in food-producing animals, include information for all four sections (Toxicology, Residue Chemistry, Microbial Food Safety, and Analytical Methods for Residues), or provide the reason(s) a particular section(s) was (were) not pertinent to the approval. For supplemental approvals, you should include a reference to previous FOI Summaries, as appropriate.

   For supplemental applications that do not include human food safety studies, use the language in the template, and include the NADA number and date of the FOI Summary that contains the information you reference.

   a. Toxicology

      This section should describe the toxicology studies that support FDA's decision to approve the new animal drug. Under the first subheading, summarize each toxicology study. You should sequentially number and individually describe each study with all the identifying information: title of study, name of study director, location of study (city and state only), brief outline of the protocol, number of animals, GLP compliance statement, and study results.

      The final three subheadings in the toxicology section (subheadings a.2 through a.4 in the template) identify the No Effect Level (NOEL) and provide the calculation of the ADI, Acceptable Single-Dose Intake (ASDI), and safe concentrations based on the toxicology studies.

   b. Residue Chemistry

      This section should describe the residue chemistry studies that support FDA's decision to approve the new animal drug. Under the first subheading, summarize each residue chemistry study. You should sequentially number and individually describe each study with all the identifying information: title of study, name of study director, location of study (city and state only), brief outline of the protocol, number of animals, GLP compliance statement, and study results.

The final three subheadings in this section (subheadings b.2 through b.4 in the template) identify the target tissue and provide the tolerance assignments and withdrawal times based on the residue chemistry studies.

c. Microbial Food Safety

The Microbial Food Safety Team will provide the text for this section.

d. Analytical Method for Residues

Describe each analytical method individually in the Analytical Method for Residues section.

I. User Safety

Copy the human warnings exactly from the approved product labeling for this section. If there are any specific user safety concerns, provide the basis for the user safety concerns including steps for minimizing the potential harm to humans handling, administering, or exposed to the new animal drug. Include a statement summarizing what we looked at (MSDS, studies, etc.) to conclude that we have had the sponsor appropriately address user safety concerns in the labeling.

J. Agency Conclusions

This section contains a summary of considerations involved in the approval of the subject drug.

In this section you should:

- Provide a detailed discussion of the basis for the approved marketing status (Rx, OTC, or VFD) for the product.[16] For drugs with Rx and VFD status, list each substantial reason why adequate directions for laymen's use cannot be written. Appendix B contains sample language.

- Note whether we granted exclusivity or not.[17] You should copy the appropriate boilerplate language from the exclusivity P&P into the FOI Summary. The boilerplate language explains why we have or have not granted exclusivity.

[16] See P&P 1240.2220 for further information about classification of OTC and Rx drugs.
[17] See P&P 1243.5780 to support the decision on granting exclusivity.

- If this is a supplemental application, identify whether the approval is a Category I or Category II change.[18] If this is an original NADA, delete this section of the template.

- Provide available patent information as submitted by the sponsor with the application or with their Labeling technical section, if applicable.

K. Attachments

Typically, you will only need to attach the labeling that the sponsor provides with the NADA. You should attach copies of the labeling components in the order you list them in this section. List the names of the labeling components identically to any name listed on the label (for example, pouch versus packet). Make sure that the labels you attach are legible.

If applicable, you should also attach the Determinative and Confirmatory Method.

X. DISTRIBUTION COPIES

You should send forward only one copy of the FOI Summary with the draft approval package.

With the final approval package you should:

- include all the necessary copies of the FOI Summary;

- write in the intended recipient of each copy, in pencil, on the title page in the upper right hand corner; and

- list the copies for distribution of the FOI Summary and appended labeling in the cc block as follows:

  cc: Document Control Unit, for the administrative file of:
  N-XXXXXX-X-XXXX
  Courtesy copy for the sponsor (no cc: block listed on this copy)
  HFV-12, FOI Staff (no cc: block listed on this copy)
  HFA-305, Division of Dockets Management (no cc: block listed on this copy)

[18] 21 CFR 514.106(b) defines the category change types.

XI. FOI SIGNATURE PAGE

Fill in the fields indicated by carat marks. If the drug is for use in non-food producing animals, insert "NA" on the Division of Human Food Safety (HFV-150) signature line (Line 4). For approvals that the ONADE Office Director signs, insert "NA" on the Center Director signature line (Line 7).

You should attach the original FOI signature page to the Document Control Unit copy of the FOI Summary in the approval package.

XII. PREPARING THE NOTIFICATION OF THE APPROVAL AND THE AVAILABILITY OF ELECTRONIC FILES

Once the primary division or staff has been notified that the approval letter has been signed, your Consumer Safety Officer or other designated person will send an email announcement center-wide. All of the information in the email will come from the title page of the FOI Summary (with the exception of the submission code).

The subject line of the email should be "ONADE Product Approval".

The body of email will consist of the following information:

NOT FOR PUBLIC DISTRIBUTION

FOR CVM EMPLOYEES ONLY

DO NOT make this information publicly available until the approval has published in the FEDERAL REGISTER.

We announce the approval of an <insert original or supplemental> New Animal Drug Application <insert NADA or ANADA number and submission code>.

<Proprietary name>

<Established name>

<Insert Dosage form>

<Species and class>

<Indications or effect of supplement>

<Sponsor's name>

XIII. REFERENCES

Statutes

Federal Food, Drug, and Cosmetic Act

21 USC §301, et seq.

Freedom of Information Act

5 USC 552

Trade Secrets Act

18 USC 1905

Code of Federal Regulations (Title 21)

Part 20 – Public Information

§20.61, Trade secrets and commercial or financial information which is privileged or confidential

Part 299 – Drugs; Official Names and Established Names

§299.4, Established names for drugs

Part 510 – Sponsors of Approved Applications

§510.600, Names, addresses, and drug labeler codes of sponsors of approved applications

Part 514 – New Animal Drug Applications

§514.1, Applications

§514.8, Supplemental new animal drug applications

§514.11, Confidentiality of data and information in a new animal drug application file

§514.106, Approval of supplemental applications

CVM Program Policy and Procedure Manual

1240.2220, Classification of OTC and Rx Drugs

1243.3010, Format and Style Conventions for Letters

1243.3030, Completing Final Action Packages for STARS Submissions

1243.5780, Exclusivity Wording for Use in the Following Documents: Memorandum Recommending Approval and Letter to Applicant

XIV. VERSION HISTORY

November 16, 2001 - ONADE Reviewers Manual revised and incorporated into CVM's Program Policy and Procedures Manual; this is the original P&P version

September 7, 2006 - Revised to update and provide a standard outline format for an NADA FOI Summary using a template, and to reorganize the General Information Section of the NADA FOI Summary.

APPENDIX 1: SAMPLE STUDY SUMMARY OUTLINE

Note: The following is a sample study summary outline. Depending on the type of study, it may be more appropriate to combine several items under a single heading, or further expand a particular heading. Try to avoid more than three levels in the outline of each study summary.

1. **Type of Study: <field study, reproductive safety, bioequivalence, etc.>**

   a. "Title" (Study No.)

   b. Investigator(s) or Study Director: *<Provide name of Clinical Investigator(s) (for clinical studies) or Study Director (for non-clinical laboratory studies), and the study location(s) - city and state>*

   c. Study Design:

1) Objective: *<description of study objective, include GLP compliance statement, if appropriate: "This study was conducted in accordance with the Good Laboratory Practice Regulations (GLPs; 21 CFR 58)." If a non-clinical laboratory study was not conducted in compliance with GLPs, provide a reason for the non-compliance and explain in what way or why the study is not compliant and why it remains acceptable.>*

2) Study Animals: *<number, breed/class, gender, age, weight, or other pertinent animal information>*

3) Treatment Groups: *<description of treatment group assignments, and dosage regimens; a table may be helpful>*

4) Drug Administration: *<description of test and control articles, treatment group assignments, and dosage regimens>*

5) Measurements and Observations: *<decision variables and other (secondary) variables/observations; include brief description of study schedule; for food safety studies, include a brief description of the method used to analyze drug residues>*

6) Statistical Methods: *<description of the statistical methods, if appropriate>*

d. Results: *<tabular format and/or descriptive>*

e. Adverse Reactions: *<description of adverse reactions, or statement such as, "No adverse reactions were reported in this study." This section does not apply to some studies, such as safety studies.*

f. Conclusion(s): *<study conclusion(s)>*

APPENDIX 2: SAMPLE STUDY SUMMARY OUTLINE

Marketing Status

Prescription (Rx) products

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because <*Provide all reasons, for example, " professional expertise is required to properly administer the injection, provide adequate instructions for post treatment care, or to monitor the safe use of the product, including treatment of any adverse reactions.*">

Over-the-Counter (OTC) products

This product can be marketed over-the-counter (OTC) because the approved labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the label are reasonably certain to be followed in practice.

Veterinary Feed Directive (VFD) products

This drug may be dispensed only under a valid Veterinary Feed Directive (VFD). Any animal feed bearing or containing this VFD drug will be fed to animals only by or on a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. <*State whether the VFDs for this drug are refillable, for example, "In addition, veterinary feed directives issued for this drug are not refillable." Also discuss why professional supervision of a licensed vet is needed.*>